

**THE SPECIFICATION AMENDMENT UPDATES THE APPLICATION'S LINEAGE AND THE PATENT FROM THE IMMEDIATE PARENT AND DOCUMENTS OF RECORD THEREIN ARE TO MADE OF RECORD IN THIS APPLICATION**

The specification is amended to update the lineage of the application, i.e., to recite that the immediate parent application is now U.S. Patent No. 5,885,607; and, to change the abbreviation for "continuation-in-part" (i.e., "CIP") to --continuation-in-part--. No new matter is added; and, the Examiner is respectfully requested to consider the prosecution of the parent applications and to consider and make of record documents cited during the prosecution of those applications, including those appearing on the face of the '607 patent, e.g., Senbo, U.S. Patent No. 5,567,429, access to which is presumed by the Examiner.<sup>1</sup>

**THE CLAIM AMENDMENTS ARE SUPPORTED BY THE APPLICATION, ARE NOT NEW MATTER, AND ARE FORMAL, FOR MORE CLEARLY DEFINING THE INVENTION DISCLOSED, WITHOUT PREJUDICE, ADMISSION, SURRENDER OF SUBJECT MATTER, OR ANY INTENTION OF ANY ESTOPPEL AS TO EQUIVALENTS**

Claims 1 to 38, 40, 42 to 48, and 50 to 81 are now pending, with claims 1, 21 and 54 being independent claims. New claim 53 is based on the disclosure throughout the application, and previous claim 49; it depends on claim 21 and provides that the pet is a cat or dog. Claims 54 to 75 are also based on the disclosure throughout the application, including page 5 of the specification and original claim 21 and the claims dependent thereon and provides a method for distributing an active agent over a pet's body and/or in sebaceous glands of the pet and thereby controlling fleas and ticks on or eliminating fleas and ticks from the pet. New claims 76 to 81 are likewise based on the disclosure throughout the application including pages 8 and 9 and the original claims such as claims 11 and 31. No new matter is added. Any fee occasioned by this

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<sup>1</sup> The Examiner is also respectfully requested to make the '607 patent, issued from the immediate parent application of record; and, any rejection based thereon in any future Office Action, e.g., such as a double patenting rejection, cannot be said to have been necessitated by this paper. Thus, any future Office Action containing such a double patenting rejection cannot be made final; and, it is respectfully requested that if the Examiner issues any future Office Action with a rejection based on the '607 patent that the future Office Action not be made final.

paper, including any extra fee claim fee for presenting additional claims may be charged or any overpayment in such a fee credited to Deposit Account No. 50-0320.

**THE SECTION 112, SECOND PARAGRAPH, REJECTION IS OVERCOME BY THE AMENDMENTS AND REMARKS**

At page 3 of the Office Action, claims 1 to 38, 40 and 42 to 52 were rejected under Section 112, second paragraph. The claims have been amended to overcome this formal rejection, without any prejudice, admission, surrender of subject matter, or any intention of creating any estoppel as to equivalents. For instance, "long lasting" is deleted from claim 43, as well as "such as" from claims 1 and 21, and hetero atoms are recited. As to  $R_3$ , it is a portion of a possible substituent for  $R_2$ . More in particular  $R_2$  can be  $S(O)_nR_3$ . Accordingly,  $R_3$  exists in the recitation of the main claims. In the dependent claims, claims 11 and 31 are amended; and, it is not believed that  $R_3$  is not recited twice in any of the dependent claims. Reconsideration and withdrawal of the Section 112, second paragraph rejection are respectfully requested.

**THE SECTION 112, FIRST PARAGRAPH, REJECTION IS OVERCOME BY THE REMARKS, ATTACHMENTS AND APPLICATION TEACHINGS**

At page 2 of the Office Action, claims 1-10, 12-14, 21-30, 32-35 and 48-52 were rejected under Section 112, first paragraph with the Examiner asserting that only compounds "A" would be operative and that undue experimentation would be required to practice the claimed invention.

The Examiner is respectfully invited to review the art and literature involving phenylpyrazoles, as well as the case law under Section 112, first paragraph.

Buntain, cited in the art rejection, shows that Applicant's exemplification with Fipronil is sufficient to support all of the embodiments of formula (I). Thus, there is no reason to doubt that by showing that Fipronil is operative as claimed, that the remainder of the class of phenylpyrazoles would not likewise similarly act.

Furthermore, phenylpyrazoles are a class of insecticides which possess excellent insecticidal activity against insect pests including blood-sucking pests such as ticks, and fleas etc., which are parasites on animals. Phenylpyrazoles are within the class of compounds known

as arylheterocycles. This class of agents kills insects by acting on the gamma-butyric acid (GABA) receptor of invertebrates (*See, e.g.,* Bloomquist, *Ann Rev Entomol*, 41:163-90 (1996) (Abstract attached).

The specification at page 5 further teaches that compounds according to formula (I) are “very lipophilic and of high vapor pressure (low volatility)”. Thus, the compounds have a very high affinity for the sebum and are taken up by the sebaceous glands. Indeed, Cochet et al., *Eur J Drug Metab Pharmacokinet* 22(3):211-6 (1997) (copy of Abstract attached) showed that fipronil, an exemplary compound within formula (I), indeed is taken up in the sebaceous glands (and epithelial layers) of animals. Since the compounds of formula (I) are “very lipophilic and of high vapor pressure (low volatility)” there is no reason to doubt that they too, like fipronil, will be taken up in the sebaceous glands (and epithelial layers) of animals.

To further illustrate the action of compounds of the invention in being taken up in the sebaceous glands, attached is “Frontline: How Frontline Works”, a copy of a printout from [www.frontline.com/products/works.html](http://www.frontline.com/products/works.html) which shows how fipronil (and ergo the formula (I) compounds) are “stored in the natural oils” and “drawn back out of follicles, re-applying itself to skin and hair” because “fipronil dissolves into the natural oils of [the] pet’s skin and coat.” Given that formula (I) compounds other than fipronil are also very lipophilic and of high vapor pressure (low volatility)” there is no reason to doubt that they too, like fipronil, dissolve into the natural oils of a pet’s skin and coat and will be taken up in the sebaceous glands (and epithelial layers) of the pet.

Hainzl et al., *PNAS USA* 93(23):1276407 (1996) (copy of Abstract attached) showed that desulfinylfipronil, the trifluoromethylpyrazole derivative of fipronil, is formed when fipronil is used as a plant insecticide (exposed to sunlight). Hainzl et al. 1996 also showed that desulfinylfipronil, the trifluoromethylpyrazole derivative of fipronil, a phenylpyrazole related to fipronil, has high neuroactivity, like fipronil and suggests that desulfinylfipronil can be a significant contributor to the effectiveness of fipronil as an insecticide for crop protection.

Since fipronil derivatives have neurotoxicity, there is no reason to doubt that compounds

of formula (I) will likewise be active against fleas and ticks. Hainzl et al. 1996 states that the trifluoromethylsulfinyl moiety of fipronil is "presumably important in its outstanding performance." In this regard, note that in formula (I) compounds, it is preferred that  $R_2$  be  $S(O)_nR_3$  with  $R_3$  being preferably alkyl or haloalkyl (application at page 7), with particular mention being made of formula (I) compounds wherein  $n=0$  and  $R_3$  is  $CF_3$ , and formula (I) compounds wherein  $n=1$  and  $R_3$  is ethyl (application at page 9). Further page 9 teaches a preferred class of compounds of formula (I) consists of those wherein  $R_1$  is CN,  $R_3$  is haloalkyl,  $R_4$  is  $NH_2$ ,  $R_{11}$  and  $R_{12}$  are, independently of each other, is a halogen atom, and/or  $R_{13}$  is haloalkyl.

Thus the skilled artisan, looking to the specification, is directed to compounds of formula (I) having the trifluoromethylsulfinyl moiety of fipronil which is recognized as "important in its outstanding performance", as well as to formula (I) compounds wherein  $n=0$  and  $R_3$  is  $CF_3$  or wherein  $n=1$  and  $R_3$  is ethyl (and thus  $R_2$  is  $S(O)_nR_3$ ), and compounds of formula (I) wherein  $R_1$  is CN,  $R_3$  is haloalkyl,  $R_4$  is  $NH_2$ ,  $R_{11}$  and  $R_{12}$  are, independently of each other, is a halogen atom, and  $R_{13}$  is haloalkyl (and thus  $R_2$  is  $S(O)_nR_3$ ), such that the specification provides a great deal of guidance, in addition to the Examples as to compounds within formula (I) that are especially useful in the practice of the invention; and, the skilled artisan would likely initially select those preferred compounds in any screening.

Further still, Hainzl et al. 1996 was followed by Hainzl et al., Chem Res Toxicol 11(12):1529-35 (1998) (copy of Abstract attached), wherein the authors showed that phenylpyrazoles related to fipronil, such as desulfinyl fipronil and fipronil sulfone, indeed acted on the GABA receptor of insects. Thus those compounds too will act as insecticides, like fipronil.

Accordingly, it is clear that compounds in addition to fipronil, within formula (I), act as insecticides; and, there is no reason to doubt that a sufficient number of compounds within formula (I) function to kill fleas and ticks. Also, it is clear that the specification provides guidance as to compounds within formula (I) which should perform like fipronil (especially

considering literature such as Hainzl et al. 1996 and Hainzl et al. 1998).

In addition, given that the insecticide mode of action of fipronil and of phenylpyrazoles within formula (I) is known (namely acting on the GABA receptor by blocking the chloride channel), no undue experimentation is required to test the insecticidal action of any compound within formula (I): One need only test compounds for this mode of action, or neuroactivity (or neurotoxicity), or for IC50; e.g., as in Hainzl et al. 1996 and Hainzl et al. 1998.

Thus, it is respectfully submitted that the assertion in the Office Action that undue experimentation is required to practice the invention as claimed is erroneous.

In this regard, the Examiner's attention is respectfully directed to Chapter 2100 of the MPEP which discusses how a Section 112, first paragraph, rejection can be made. An issue in a Section 112, first paragraph, rejection is whether undue experimentation is required to practice the invention as claimed.

Whether experimentation is required to practice the invention is not the issue; but rather, the issue is whether the experimentation required is undue.

Determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), e.g., (1) The quantity of experimentation necessary; (2) The amount of direction or guidance presented; (3) The presence or absence of working examples of the invention; (4) The nature of the invention; (5) The state of the prior art; (6) The relative skill of those in the art; (7) The predictability or unpredictability of the art; and (8) The breadth of the claims.

In the present situation, to determine whether a formula (I) compound will work the skilled artisan need only ascertain that it has the "very lipophilic and ...high vapor pressure (low volatility)" characteristic and the activity on the GABA receptor by blocking the chloride channel or a suitable IC50 value; for instance, by techniques of Hainzl et al. 1996 or Hainzl et al. 1998, or other techniques known at the time of filing (*see also* Bloomquist, which recognized that fipronil blocks the GABA-gated chloride channels). Testing a collar product containing a compound found by these simple screens for six months also does not require undue

experimentation: consumer products are often tested for shelf life without such duration tests considered undue experimentation.

Indeed, under *Wands*, routine experimentation, even if time-consuming (such as screening numerous hybridomas) is not considered undue experimentation.

Thus, the quantity of experimentation does not require great amounts of time or expense.

Given the disclosure in the application of formula (I) compounds, especially preferred compounds, and the disclosure in the Examples, as well as the knowledge in the art, the application provides a great amount of guidance and working examples.

The state of the art is such that from the present application, the skilled artisan can perform tests to determine if a particular compound indeed works within the claims, especially considering there is a body of literature already existing with respect to phenylpyrazoles as insecticides; and, those skilled in the art are highly skilled PhDs.

And thus, the claims are not unduly broad; and, no undue experimentation is required to practice the invention as claimed.

The Examiner is also respectfully requested to note that compliance with 35 U.S.C. 112, first paragraph does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. An applicant need not have actually reduced the invention to practice prior to filing. *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987): "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."

Indeed, a specification need not contain any example of the invention, as the issue is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970).

An applicant need not describe all actual embodiments of a claimed invention. The first paragraph of Section 112 does not require a specific example of everything within the scope of a

broad claim. *In re Anderson*, 176 U.S.P.Q. 331, 333 (C.C.P.A 1973). This is true even in an unpredictable art. *In re Obukowitz*, 27 U.S.P.Q. 2d 1063, 1067 (BOPAI 1993). Such a requirement would have an adverse affect on the patent system. *See In re Angstadt and Griffin*, 190 U.S.P.Q. 214, 218 (C.C.P.A., 1976) (to require a disclosure of every species covered by a claim would force an inventor to carry out a prohibitive number of experiments, and would allow potential infringes to avoid literal infringement by merely finding an analogous embodiment not expressly disclosed)); *In re Goffe*, 191 U.S.P.Q. 429, 431 ("To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials in a process . . . . would not serve the constitutional purpose of promoting progress in the useful arts.").

The Section 112, first paragraph, rejection, it is respectfully submitted, is contrary to the law as it attempts to limit Applicant to only exemplified embodiments, without appreciating that the disclosure in the application, accompanied by the knowledge in the art, is sufficient for the skilled artisan to select other formula (I) compounds (than fipronil) without undue experimentation (especially considering that other phenylpyrazoles related to fipronil are shown to have the same mode of action and insecticidal activity).

Furthermore, in order to make a Section 112, first paragrph, rejection, the Examiner has the initial burden to establish a reasonable basis to question the enablement or scope provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

The Office Action fails to establish such a reasonable basis for questioning enablement or scope, especially considering the foregoing and the attachments.

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented (i.e., the claim language) must be taken as being in compliance with 35 U.S.C. §112, first paragraph, unless there is a reason to doubt the

objective truth of the statements contained in the application.

The Office Action fails to supply any sufficient reason for doubting that the formula (I) compounds other than Fipronil would function as claimed, especially in view of the foregoing discussion and the attachments. That is, the Office Action fails to set forth any reason why the application fails to teach how to make and/or use the invention, in view of the broad and enabling disclosure of the in the application and the knowledge in the art. *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971): "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *See also In re Bowen*, 492 F.2d 859, 181 USPQ 48 (CCPA 1974).

Accordingly, when the application is considered as a whole, and all of its teachings are appreciated, in light of the case law and the knowledge in the art, there is no doubt that the claims meet the requirements of Section 112.

Reconsideration and withdrawal of the Section 112, first paragraph, rejection, are respectfully requested.

**THE ART REJECTION IS OVERCOME BY THE CLAIM  
RECITATIONS, IN VIEW OF THESE REMARKS, AND THE  
ATTACHMENTS, THE APPLICATION TEACHINGS, AND CASE LAW**

At pages 4 to 5, the Office Action rejects the claims under Section 103(a) as unpatentable over Buntain.

Buntain at page 7 mentions "ear tags". Further, Buntain, at page 7, mentions that the "ear tags" are attached externally "in such a way as to provide local or systemic arthropod control." At page 11, in composition Example 12, Buntain mentions "strips" for "fabrication into collars or ear-tags ... to control pests by slow release of the pyrazole compound." There is no teaching or suggestion in Buntain of a collar as preferable over ear tags, whereas "collar" is recited in each



of the independent claims in the present application.

Moreover, Cochet et al. (copy of Abstract attached) states that application topically of fipronil did no result in detection of fipronil “in either the dermal or the hypodermal layers”; that is “low percutaneous passage of fipronil”.

Further, the present application teaches that the application of formula (I) compounds by way of a collar, as in the present claims, results in distributing an the formula (I) compound over a pet’s body and/or in sebaceous glands of the pet to control or eliminate fleas and ticks (*see also* Cochet et al. teaching that fipronil applied topically is mainly in the sebaceous glands and epithelial layers of the animal, and “Frontline: How Frontline Works”).

Accordingly, there is neither local nor systemic activity of the formula (I) compounds by the collars and methods of the invention; contrary to Buntain. Further, the mode of action according to the composition and method claims of the present invention is not “by slow release” as indicated by Buntain; but rather, by dissolution into the oils of the skin and hair and re-application when drawn out of the follicles.

The mode of action being by dissolution into the oils of the skin and hair and re-application when drawn out of the follicles means that the “collar” recitation of the independent claims is quite meaningful: an ear tag may not provide access to oils of the skin and hair and follicles as readily as a collar; and thus, an ear tag may not provide as rapid a distribution over the pet’s body as a collar. The fact that Buntain equates ear tags and collars means that Buntain fails to teach, suggest or recognize the surprising superiority of the present invention in collar form and when the methods of the present invention are practiced with a collar; and ergo, that Buntain fails to teach or suggest the present invention. In contrast to Buntain, and as a patentable distinction over Buntain, the independent claims recite “collar”.

Indeed, in addition to each of the independent claims reciting “collar”, note too that claim 54 provides that the method recited therein is for distributing an active agent over a pet’s body and/or in sebaceous glands of the pet to control or eliminate fleas and ticks; and, likewise, claim 1 recites that the claimed collar is for distributing an active agent over a pet’s body and/or in

sebaceous glands of the pet to control or eliminate fleas and ticks. The method of claim 54 and the claims dependent thereon and the collar of claim 1 and the claims dependent thereon are especially not taught or suggested by Buntain, since distribution over the pet's body and/or in sebaceous glands of the pet is neither local nor systemic and nor is it "slow release".

Again, in contrast to the present claims, Buntain teaches "local or systemic arthropod control" and "slow release of the pyrazole compound" from a "strip[] fabricat[ed] into [a] collar[] or ear-tag[]." As shown by the discussion herein, the attachments herewith, and as disclosed in the present application, the mode of action is neither local nor systemic and is not by a "slow release". Further, as discussed above, given that the formula (I) compounds distribute over a pet's body and/or in sebaceous glands of the pet to control or eliminate fleas and ticks, i.e., given that the mode of action is by dissolving into skin and hair oils and storage in the sebaceous glands, a collar can be superior to an ear tag; and, Buntain, in addition to failing to recognize the mode of action, fails to recognize any superiority of a collar, at best equating it to an ear tag.

The Examiner is respectfully reminded that: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). And, it is respectfully requested that each and every recitation of each and every claim be fully considered.

In *In re Swinehart*, 169 U.S.P.Q. 227 (C.C.P.A. 1971), the "point of novelty" was "transparen[cy]" and the Court, in holding that "functional" or "use" language was permissible, even at the "point of novelty" stated:

We take the characterization "functional" ... to indicate nothing more than the fact that an attempt is being made to define something ... by what it *does* rather than by what *is* ... . In our view, there is nothing intrinsically wrong with the use of such a technique in drafting patent claims ...

*Id.* at 228.

In *In re Duva*, 156 U.S.P.Q. 90 (C.C.P.A. 1967), the composition claimed was an

aqueous solution "for depositing gold" and in reversing the prior art rejection based upon a failure by the PTO to consider the "for depositing gold" recitation because it was an "intended field of use" limitation, the Court held:

[A]ll factual differences which may be properly noted in any portion of a claim must be included within the basis for comparison with the prior art if we are to properly evaluate the *difference* between the invention defined in a claim and the teachings of a reference. The command of 35 U.S.C. 103 is to compare the invention *as a whole* with the prior art. Absent a failure of the applicant to comply with 35 U.S.C. 112, **we think every portion of the appealed claims must be considered ...**

*Id.* at 94 (emphasis in original and added).

Furthermore, it is well-established law that where the preamble is essential to point out the claimed invention and give meaning and vitality to the claim, it is given the effect of a limitation. *Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 U.S.P.Q.2d 1315 (Fed. Cir. 1988); *In re Tuominen*, 671, F.2d 1359, 213 U.S.P.Q. 89 (**sunscreen composition**) (C.C.P.A. 1982); *In re Bulloch et al.*, 604 F.2d 1362, 203 U.S.P.Q. 171 (C.C.P.A. 1979) (**stable color developer concentrate**); *In re Szajna et al.*, 422 F.2d 443, 164 U.S.P.Q. 632 (C.C.P.A. 1970); *In re Walles et al.*, 366 F.2d 786, 151 U.S.P.Q. 185 (C.C.P.A. 1966); ("**a composition for setting hair**"); *Smith v. Bousquet*, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940) (**insecticide composition**); *Ex parte Varga*, 189 U.S.P.Q. 204 (P.O.B.A. 1973); *see also Kropa v. Robie et al.*, 187 F.2d 150, 88 U.S.P.Q. 478 (C.C.P.A. 1951); *Duva*.

In the present situation, the preamble recitations of the collar and method claims are clearly limitations of the claims which must be considered and given weight as patentably distinguishing the claimed invention.

In regard to this, the Examiner is respectfully invited to review U.S. patents that have issued in the animal health arts, especially recently-issued U.S. patents, as it is believed clear that preamble recitations as in the present claims have been accorded weight as patentably

distinguishing claims from prior art.

Furthermore, the Examiner's attention is respectfully directed to additional case law.

*In re Marshall*, 578 F.2d 301, 198 U.S.P.Q. (C.C.P.A. 1978) dealt with method claims for orally administering a compound in amounts sufficient to produce body weight loss. Some specific claims recited a range of the amount to be taken daily for producing weight loss. The prior art, the Physician's Desk Reference (PDR) disclosed the same compounds for oral administration for treating ulcers and other gastrointestinal problems. The rejection was under Section 102 (and, it is noted that art must be available under Section 102 before it can be used in a Section 103 rejection).

The C.C.P.A. reversed the rejection, stating that, "If anyone ever lost weight by following the PDR teachings, it was an unrecognized accident. **An accidental or unwitting duplication of an invention cannot constitute an anticipation.** *In re Felton*, 484 F.2d 495, 500, 179 U.S.P.Q. 295, 298 (C.C.P.A. 1983)" (emphasis added).

The mere fact that a reference's generically disclosed structure might fortuitously have been built in accordance with the narrower limitations of a later claim cannot constitute anticipation. *In re Felton* (cited by the C.C.P.A. in *Marshall*, above); *Tilghman v. Proctor*, 102 U.S. 707 (1880); *Eibel Process Co. v. Minnesota and Ontario Paper Co.*, 261 U.S. 45 (1923). **Moreover, even if a reference disclosure inevitably produces the claimed subject matter, if it is produced in such a manner as to go unnoticed and undetected, the reference cannot constitute an anticipation under Section 102.** *In re Seaborg (I)*, 328 F.2d 993, 140 U.S.P.Q. 659 (C.C.P.A. 1964); *In re Seaborg (II)*, 328 F.2d 996, 140 U.S.P.Q. 662 (C.C.P.A. 1964).

The Examiner's attention is further directed to cases such as *The General Tire & Rubber Co. v. Jefferson Chem. Co., Inc.*, 182 U.S.P.Q. 70 (2d Cir. 1974), *In re Antonson*, 124 U.S.P.Q. 132 (C.C.P.A. 1959), *International Nickel Co. v. Ford Motor Co.*, 119 U.S.P.Q. 72 (S.D.N.Y. 1958), and *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923) for the classic holding that invention resides in recognizing a problem, as well as providing a solution. **Indeed, in *Eibel* the Supreme Court recognized that accidental results, not intended and**

**not appreciated do not constitute anticipation.** See also *General Tire*, 182 U.S.P.Q. at 76. In *International Nickel*, the Court stated (with emphasis): "**Where the allegedly anticipating product was produced by chance and never recognized nor appreciated, one who later discovers and recognizes the product may patent it.**" 119 U.S.P.Q. at 80.

In the present case, it is Applicant who recognized that phenylpyrazoles can be employed in a collar for distributing an active agent over a pet's body and/or in sebaceous glands of the pet to control or eliminate fleas and ticks; and that the collar can be used in a method for distributing an active agent over a pet's body and/or in sebaceous glands of the pet to control or eliminate fleas and ticks. There is no such recognition in Buntain; and, indeed, by equating "collar" and "ear tag" and by teaching local or systemic action (neither of which is occurring in the present invention) as well as "slow release", Buntain teaches away from the present invention. Any prior art "device" or method which may have included a phenylpyrazole- was not a composition or method of the invention and could not, under the case law, be a teaching or suggestion of the present invention.

Thus, the recitations of the claims **MUST** be fully considered as patentably distinguishing the claimed subject matter from the prior art as there is no appreciation or recognition of that subject matter in the prior art (e.g., Buntain).

The Examiner's attention is further respectfully directed to case law; namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the primary reference in the manner suggested by the Examiner. *In re Laskowski*, 12 USPQ 2d 1397, 1399 (Fed. Cir. 1989). Again, given that Buntain does not relate to a "collar" *per se* but rather equates collars and ear tags. Buntain does not relate to distributing an active agent over a pet's body and/or in sebaceous glands of the pet to control or eliminate fleas and ticks (but rather mentions local or systemic action and slow release). There is no incentive or motivation for modifying Buntain.

Also, it is noted that, "obvious to try" is not the standard under 35 USC §103. *In re Fine*, 5 USPQ 2d 1596, 1599 (Fed. Cir. 1988). But for the exemplification in the application, the

skilled artisan would have had no reasonable expectation of success that a phenylpyrazole in a collar would be useful for distributing an active agent over a pet's body and/or in sebaceous glands of the pet to control or eliminate fleas and ticks.

Further, as stated by the Court in *In re Fritch*, 23 UPPQ 2d 1788, 1783-1784 (Fed. Cir. 1992):

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.

Buntain fails to provide the necessary incentive or motivation for modifying its teachings; and, as mentioned above, teaches away from the present invention.

It is respectfully requested that the art rejection under Section 103 be reconsidered and withdrawn.

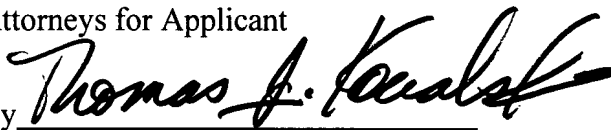
**REQUEST FOR INTERVIEW**

Additionally, if the Examiner is of the view that any issue remains as an impediment to allowance, prior to the issuance of any paper other than a Notice of Allowance, an interview is respectfully requested, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time therefor.

**CONCLUSION**

In view of the amendments, remarks and attachment herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,  
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**FRONTLINE**

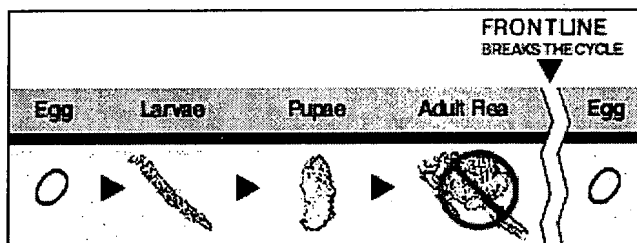
SUPERIOR FLEA &amp; TICK PROTECTION FOR YOUR PET



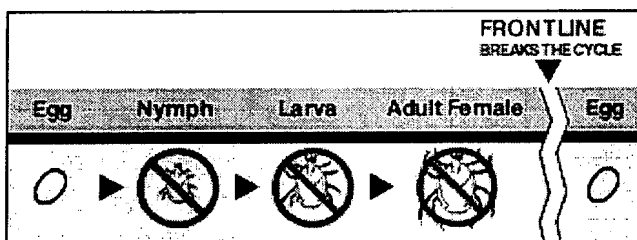
## How FRONTLINE Works

When you apply FRONTLINE to your pet, the active ingredient Fipronil is stored in the natural oils of his/her skin and coat. This provides your pet with protection against fleas and ticks for a month -- even after a whole lot of baths and shampoos (or as many as your pet will sit still for!). In fact, your pet can romp in the rain, splash in the surf and get soaked to his/her happy heart's content without losing any protection against fleas and ticks.

Unlike other products which work only after fleas or ticks have bitten your pet, FRONTLINE kills 'em soon after contact. The flea and tick life cycles are then broken because the adults die before they can lay any of their eggs.

[Home](#)
[FRONTLINE Products](#)
[How FRONTLINE Works](#)
[FRONTLINE vs. Other Products](#)
[FRONTLINE TOP SPOT™](#)
[FRONTLINE Spray](#)
[Flea & Tick Info](#)
[Pet Central](#)
[E-mail Reminder](#)
[FRONTLINE Q & A](#)


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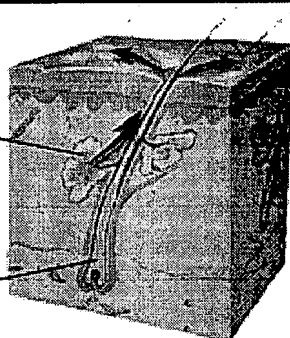
Want to learn more about ticks? [Click here!](#)

Your pet won't need separate flea and tick control products because FRONTLINE gets the whole job done all by itself. Yet it's gentle enough to be used on puppies and kittens.

### FRONTLINE in action

Sebaceous glands provide a natural reservoir for FRONTLINE

FRONTLINE is drawn back out of follicles, re-applying itself to skin and hair.



The small dose of fipronil dissolves into the natural oils of your pet's skin and coat. From there, it works its way over and around your pet's body and provides your pet with long-lasting flea and tick protection -- even after repeated shampooing, swimming or frolicking through puddles.

[TOP](#)

[Home](#) | [FRONTLINE Products](#) | [Flea & Tick Info](#)  
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